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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/416,384	10/12/99	BLUMENFELD	M BENSET.04AU

EXAMINER

ART UNIT	PAPER NUMBER
1711	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/416,384	Blumenfeld et al
Examiner	**Group Art Unit**
Jeffrey Fredman	1655

☒ Responsive to communication(s) filed on *Sep 28, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-73* is/are pending in the application.

Of the above, claim(s) *1-44 and 47-57* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *45, 46, and 58-73* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *9*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group IV, claims 45 and 46 in Paper No. 10 is acknowledged.

Applicant correctly elects two species, SEQ ID Nos: 5 and 7, which are certainly less than 10 sequences and which will both, therefore, be examined to the extent possible.

Sequence Rules

2. This application complies with the Sequence Rules and the sequences were entered by the Scientific and Technical Information Center.

Specification

3. The examiner cannot understand the invention because certain portions of the disclosure are illegible. The illegible portion(s) consist of the tops of pages 117-124 where insufficient space was left for hole punching and the holes were punched through words.

Applicant is required to submit an appropriate amendment rectifying this deficiency. In the alternative, a substitute specification under 37 CFR 1.125(b) may be filed. The substitute specification must be accompanied by: (1) a statement that the substitute specification contains no new matter; and (2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 45, 46, and 58-73 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The current claims are drawn to a genus of polypeptides termed G713 proteins in the specification, antibodies against the G713 proteins, and a method of use of the antibody for detection of the G713 protein.

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of the proteins. The only cited utilities identified by the examiner are to detect the protein itself, to make antibodies and to screen drugs. These utilities are credible.

Upon identification of credible utilities, the next issue is whether there are any well established utilities for the protein. No well established utilities for this specific G713 protein are identified in either the specification or in the cited prior art.

Given the absence of a well established utility, the final issue is whether substantial and specific utilities are disclosed in the specification. Here, no substantial utilities which are specific to this protein are identified. As noted in the utility guidelines, methods of treating unspecified

diseases, basic research on a product to identify properties, intermediate products which themselves lack substantial utility are all insubstantial utilities. No substantial utility is identified for the specific G713 proteins of the specification, with only speculative utilities that lack any basis provided. Further, none of the recited utilities in the specification are specific to the G713 protein. None rely on any unique feature of this protein.

Finally, with regard to the utility analysis, the current situation directly tracks Example 4 of the utility guidelines, where a protein of entirely unknown function was characterized as lacking utility.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 45, 46, and 58-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to a genus of any G713 proteins which have a specified component of specific SEQ ID Nos 5 and 7, or encoded by SEQ ID Nos 4 and 6, or antibodies thereto which either have specific binding domains, and proteins comprising portions of those previous. This large genus is represented in the specification by only the named SEQ ID Nos.

Thus, applicant has express possession of only two different amino acid species and two nucleic acid species in a genus which comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided.

Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleic acid and amino acid sequence of the disclosed SEQ ID Nos are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of any nucleic acids acids modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID Nos. No correlative function which permits any determination of whether the same protein is made is disclosed in the specification.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 45 is rejected under 35 U.S.C. 102(b) as being anticipated by Wimmer et al (Nature (1993) 366:690-694).

Wimmer teaches an isolated polypeptide which comprises 6 contiguous amino acids of SEQ ID NO: 5 (see page 692, figure 2, panel e).

```
  Query Match             6.8%;  Score 168.5;  DB 2;  Length 644;
  Best Local Similarity   37.7%;  Pred. No. 8.9e-05;
  Matches   43;  Conservative   14;  Mismatches   26;  Indels   31;  Gaps
4;

Qy      72 HQQQQRQ------QQQQQQQQRQRQQQQQQRRQQEPSWPALLASMGESSPAAQAHRLLSA 125
           |||  |:|      |||||||||:|:|||||||::||:|                | |  |||
Db      50 HQQAQQQHMQHLTQQQQQQQQQQQQQQQQQQQQQQQPQ--------------QQQHDFLSA 95
```

10. Claims 45 and 69 are rejected under 35 U.S.C. 102(a) as being anticipated by Bartsch et al (WO 9932615).

Bartsch teaches an isolated polypeptide which comprises 10 contiguous amino acids of SEQ ID NO: 7 overlapping amino acids 63-113 (see figure 1a).

```
  Query Match             8.1%;  Score 202;  DB 20;  Length 910;
  Best Local Similarity   33.0%;  Pred. No. 5.8e-09;
  Matches   60;  Conservative   20;  Mismatches   50;  Indels   52;  Gaps
7;

Qy      65 TRTRDKEHHQQQQQQQQQQQQQQQQQQQQQQRQQQRQRQQQRQRQQEPSWPALLASMGES 124
           :: :  :   |||||||||||||||||||:|||:|:|||:|:||:|  |      | |
Db     729 sqvqqtqtqtqqqqqqqqqqqqqqqqqqqqqqqqqqqqqqqqqqpqtp------gss 782
```

Claim Rejections - 35 USC § 102/103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 45, 46 and 58-73 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hanson et al (J. Exp. Med. (1992) 176:565-573)..

Hanson teaches a protein of 50 kD which is found in neuronal cells as well as antibodies which immunoreact with this protein (abstract). Hanson further teaches an assay in which the antibodies are incubated with a sample in order to determine whether the protein is present or absent (abstract).

Regarding 102/103 rejections, the MPEP 2112 states

" A REJECTION UNDER 35 U.S.C. 102 / 103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same

as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102 / 103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best,195 USPQ 430, 433 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, 35 U.S.C. 102 / 103 rejection is appropriate for these types of claims as well as for composition claims.

EXAMINER MUST PROVIDE RATIONALE OR EVIDENCE TENDING TO SHOW INHERENCY

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented . It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." Id. at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

> "The PTO can require an applicant to prove that the prior art products do not necessarily possess the characteristics of his [or her] claimed product. ***Whether the rejection is based on `inherency' under 35 U.S.C. 102, on `prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same." The burden of proof is similar to that required with respect to product - by - process claims. In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980) (quoting In re Brown,173 USPQ 685, 688 (CCPA 1972))."

Here, Hanson teaches all of the characteristics of the claimed protein disclosed in the specification, with the sole exception of the sequence, which is an inherent property of the protein. The claimed protein has only two identifiable characteristics, it's predicted molecular weight of approximately 50 kd, and it's location in neuronal type cells. Hanson meets both of these limitations, so that the Hanson prior art is silent regarding the inherent characteristic of protein sequence. Since the examienr has shown a reference product that, based upon the only characteristics available is identical to the protein claimed, the burden shifts to the applicant to show an unobvious difference.

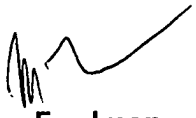
Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Fredman, Ph.D. whose telephone number is (703) 308-6568.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Group 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



Jeffrey Fredman
Primary Patent Examiner
Art Unit 1655

October 24, 2000